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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

10/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,819	Applicant(s) WATANABE ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09/23/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/23/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 11 is rejected under 35 U.S.C. § 101 because it appears to embrace more than one statutory class of invention. Claims which are intended to embrace both product or machine and process is precluded by language of 35 USC 101, which sets forth statutory classes of the invention in the alternative only. Claim 6 is directed to the apparatus, however claim 11, dependent thereon, recites the step of anastomosis manipulation while in grasping the tissue with the device, and thus appear to be directed to a process. As such, claim 11 appears to embrace multiple statutory classes of invention which is prohibited (See Ex parte Lyell, 17 USPQ2d 1548 (1990)).

Claim Rejections - 35 USC § 112

3. Claims 1-3 and 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 1 recites the limitation "the first grasping portion of the first grasping plate" in lines 19-20. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, the first grasping portion of the first grasping plate has been taken to mean the opening of the first grasping plate since is located opposite the covering portion of the second grasping plate for grasping the tissue.
5. Claim 11 is invalid under 35 USC 112, second paragraph, since a claim which purports to be both machine and process is ambiguous and therefore does not particularly point out and distinctly claim the subject matter of the invention. Ex parte Lyell, 17 USPQ2d 1548 (1990). In

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that claim 11 directed to the process rather than the apparatus of claim 6, these claims will not be further treated on the merits thereof.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

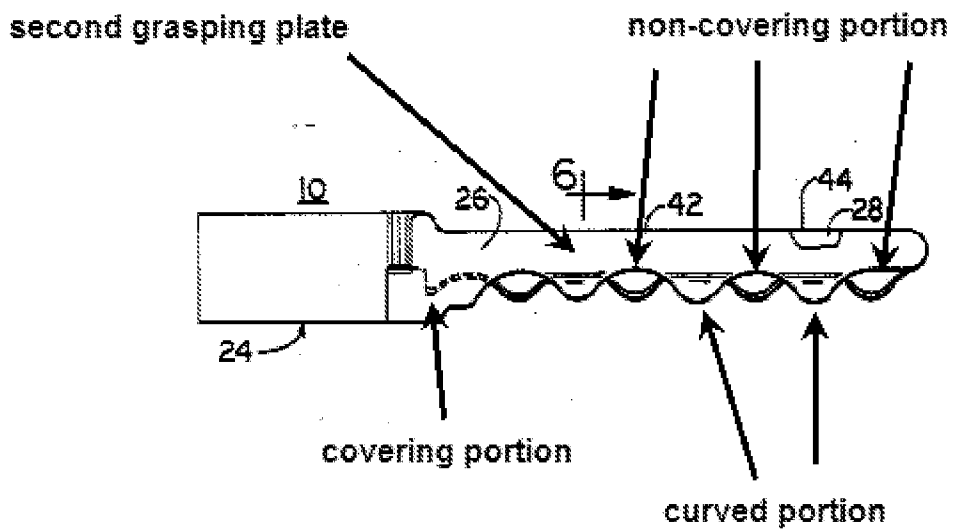
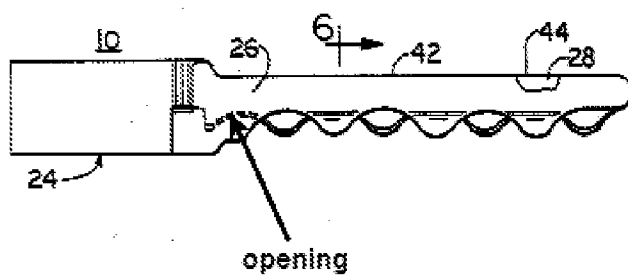
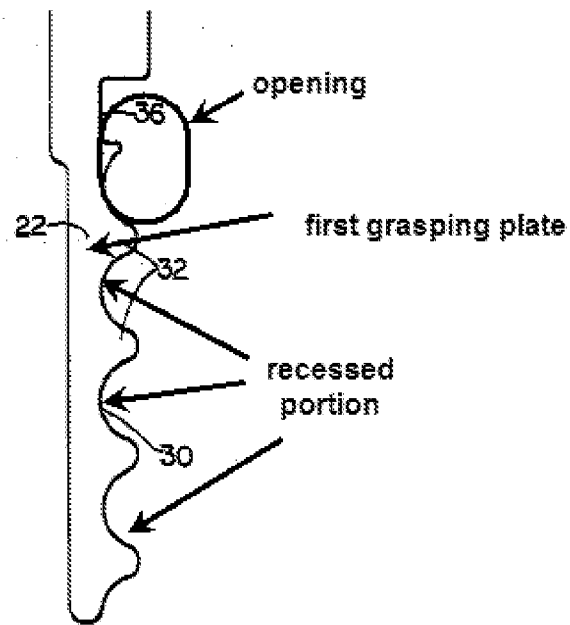
7. Claim 1, 5, and 6-10, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Kees, Jr. et al. (US 4,340,061).

Regarding claims 1 and 6, Kees, Jr. et al. disclose a surgical holder comprising a grasping member (20, 22) for grasping a tissue, a manipulation member (24) for manipulating the grasping member (20, 22), and a connection portion (see figure below) with one end connected to the manipulation member, wherein: the grasping member includes a first grasping plate (22), and a second grasping plate (20) provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other; the first grasping plate includes a retaining portion having an opening (see figure below) of a U- shape or substantially a U-shape which is opened toward an outer side of the first grasping plate and a supporting portion having a recessed portion (rounded scallops 30 of first grasping plate 22; see figure below), the opening being provided in one end of the first grasping plate and the recessed portion being provided in the other end of the first grasping plate, the second grasping plate includes a covering portion (see figure below) formed so as to cover an entire surface or a part of the opening of the first grasping plate, a non-covering portion (rounded scallops 30 of second grasping plate 20; see figure labeled below) which does not

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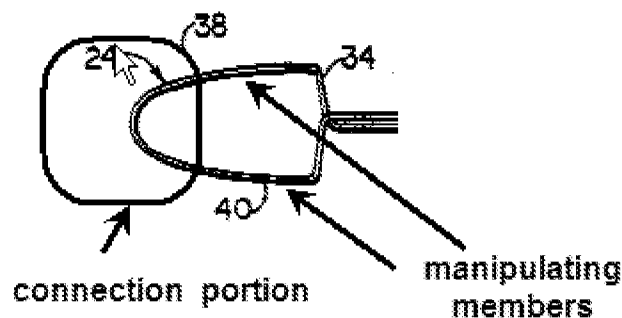
cover the first grasping plate, and a fixing portion having a curved portion (see figure below), the covering portion being provided in one end of the second grasping plate and the curved portion being provided in the other end of the second grasping plate, the curved portion opposing the recessed portion to form the tissue grasping space when the first grasping plate and the second grasping plate are positioned so as to oppose on another (Fig. 1), a first grasping portion which can grasp a part of a tissue between the opening of first grasping plate and the covering portion of the second grasping plate is provided in one end portion of the grasping member, and the opening exposing another part of the tissue when the part of the tissue is grasped by the first grasping portion; and a second grasping portion which can form a tissue grasping space between the recessed portion of the first grasping plate and the curved portion of the second grasping plate provided in another end portion of the grasping member.

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Regarding claim 5, Kees, Jr. et al. disclose surgical holder comprising a grasping member (20,22) for grasping a tissue, a manipulation member (see figure below) for manipulating the grasping member, and a connection portion (see figure below) with one end connected to the manipulation member and the other end provided with a fixing tool (clip handling tool, col. 2, ln. 26-28), wherein: the grasping member includes a first grasping plate (22), and a second grasping plate (20) provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other; the grasping member is formed into a rectangular shape with the manipulation member elongated from a side thereof (Fig. 3-4); a first grasping portion which can grasp a part of a tissue between the first grasping plate and the second grasping plate, and an opening (see figure above), provided in the vicinity of the first grasping portion and exposing another part of the tissue, is provided in one end portion of the grasping member, the opening being opened at an outer side of the first grasping portion; and a second grasping portion which can form a tissue grasping space between the first grasping plate and the second grasping plate (between curved and recessed portions labeled above) provided in another end portion of the grasping member, the tissue grasping space and the opening being positioned at respective ends on one axis of the grasping member.



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Regarding claim 7, the device of Kees, Jr. et al. is capable of grasping a tubular tissue with a surrounding tissue, and the part which defines the shape of the opening of the first grasping plate and the covering portion of the second grasping plate is capable of grasping the surrounding tissue.

Regarding claim 8, the device of Kees, Jr. et al. is capable of grasping a tubular tissue, and a tissue grasping space formed by the recessed portion of the first grasping plate and the curved portion of the second grasping plate is capable of grasping the tubular tissue.

Regarding claim 9, the device of Kees, Jr. et al. is capable of grasping a tubular tissue, and the retaining portion of the first grasping plate and the covering portion of the second grasping plate is capable of grasping the tubular tissue at one point of the tubular tissue and a tissue grasping space formed by the recessed portion of the first grasping plate and the curved portion of the second grasping plate is capable of grasping another point of the tubular tissue. Regarding claim 10, the device of Kees, Jr. et al. is capable of grasping a tubular tissue by inserting an end portion of the retaining portion which defines the opening of the first grasping plate into a tube of the tubular tissue.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kees, Jr. et al. (US 4,340,061) in view of Mandel et al. (US 2002/0177863).

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Regarding claim claims 2 and 3, Kees, Jr. et al. fail to disclose a tissue protection material is attached to an opposing surface of the first grasping plate and/or the second grasping plate, wherein the tissue protection material is permeated with medicines. Mandel et al. disclose providing an antimicrobial and/or antibiotic coating to the surfaces of a ligating clip in order to prevent and kill microorganisms in the area of the clip (paragraphs 33 and 34). It would have been obvious to one of ordinary skill in the art to modify the clip of Kees, Jr. et al to include a tissue protecting coating containing antibiotic or anti-microbial materials or medicines in order to prevent growth and to kill microorganisms in the area of the clip.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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09/29/2009

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734